

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/767,561

Applicant(s)

FREEMAN ET AL.

Examiner

Phillip Gambel

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 17 January 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-14.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☒ Other: See Continuation Sheet.

/Phillip Gambel/
Primary Examiner, Art Unit 1644
03/10/2008

Continuation of 11. does NOT place the application in condition for allowance because: essentially for the reasons of record. Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Again, with respect to applicant's arguments concerning the Written Description rejection under 35 USC 112, first paragraph, the following is noted.

While applicant asserts a teaching of a correlation between chemical structure and function, by using the chemical structure and function of human B7-2 to isolate and characterize murine B7-2 (see Example 6 of the amended specification, incorporated by reference from U.S.S.N. 08/280,757, now U.S. Patent No. 6,130,316). Applicant relies upon Example 6 shows that the structural and functional information gained during the isolation of human B7-2 can readily be applied to isolate B7-2 from other species - in this case the mouse. Specifically, CTLA4-Ig and CD28-Ig were used to isolate B7-2 expressing cells, and an anti-B7-1 monoclonal antibody (mAb) was used to remove B7-1 expressing cells. Applicant asserts that these detailed methods demonstrate that the structural characteristics and functional criteria defined in the claims are sufficient to isolate and define B7-2 molecules that are at least 50% homologous, and that B7-2 can readily be distinguished from the related family member B7-1. Applicant asserts that a person of ordinary skill in the art would thus readily recognize that methods that are essentially identical to those used in Example 6 could also be used to isolate other B7-2 species and, hence, that the claimed methods fall well-within the scope of the written description provided in the specification.

Applicant's arguments, including attempts to distinguish certain legal decisions and the references relied upon in the Written Description Rejection of record have been fully considered but have not been found convincing essentially for the reasons of record.

Again, with respect to applicant's reliance upon various screening assays, the Court has held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of which peptides, polynucleotides, or small organic molecules have the desired characteristic, the claims failed to meet the description requirement of § 112. See *University of Rochester v. G.D. Searle & Co., Inc.*, 69 USPQ2d 1886,1895 (Fed. Cir. 2004).

As noted previously, the problem here is that the instant specification fails to provide a disclosure of which residues are required for the B7-2 molecule and fragments thereof that would retain the ability to costimulate a T cell and the ability to bind a CD28 or CTLA4in B7-2 molecules and fragments thereof, other than the those B7-2 molecules isolated and cloned from a murine B cell tumor line M12 or from human anti-IgM activated B cells.

A skilled artisan cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus that exhibit this functional property.

Therefore, there is insufficient written description for genus of "B7-2 molecules comprising a limited sequence of nucleic acids encoding 20 amino acids or having 50% homology" to essentially two (2) examples of functional B7-2 molecules isolated and cloned from a murine and human cells, broadly encompassed by the claimed invention at the time the invention was made and as disclosed in the specification as filed under the written description provision of 35 USC 112, first paragraph..

Continuation of 13. Other: The Sequence Listing could NOT be accepted. See Attached Validation Report .